

Amendment to the Specification

Please replace paragraph [0025] with the following amended paragraph:

An "antioxidant" used in the present invention includes nitrite (e.g., sodium nitrite), sulfite (e.g., sodium sulfite, dried sodium sulfite, sodium hydrogen sulfite, and sodium pyrosulfite), thiosulfate (e.g., sodium thiosulfate), alpha-thioglycerin, 1,3-butylene glycol, thioglycolic acid and salts thereof (e.g., sodium thioglycolate), thiomalate (e.g., sodium thiomalate), thiourea, thiolactic acid, edetate (e.g., sodium edetate), dichloroisocyanurate (e.g., potassium dichloroisocyanurate), citric acid, cysteine and salts thereof (e.g., cysteine hydrochloride), benzotriazole, 2-mercaptobenzimidazole, erythorbic acid and salts thereof (e.g., sodium erythorbate), ascorbic acid and ester compounds thereof (e.g., L-ascorbyl stearate and ascorbyl palmitate), phospholipid (e.g., soybean lecithin), metal chelating agents and salts thereof (e.g., ethylenediaminetetraacetic acid, calcium disodium ethylenediaminetetraacetate, and disodium ethylenediaminetetraacetate), tartaric acid and salts thereof (e.g., Rochelle salt), polyphenols (e.g., catechin), glutathione, dibutylhydroxytoluene, butylhydroxyanisole, propyl gallate, natural vitamin E, tocopherol acetate, concentrated mixed tocopherol, and tocopherol homologues

(e.g., d- $\alpha$ -tocopherol, dl- $\alpha$ -tocopherol, 5,8-dimethyltolcol, 7,8-dimethyltolcol,  $\delta$ -methyltolcol, 5,7,8-trimethyltocotrienol, 5,8-dimethyltocotrienol, 7,8-dimethyltocotrienol, and 8-methyltocotrienol). These antioxidants can be used alone or in combination of 2 or more of them. The antioxidant is preferably one member selected from tocopherol acetate, dibutylhydroxytoluene, natural vitamin E, dl- $\alpha$ -tocopherol, d- $\alpha$ -tocopherol, concentrated mixed ~~tocopherol~~tocopherols, ascorbyl palmitate, L-ascorbyl stearate, butylhydroxyanisole, and propyl gallate, and more preferably, one member selected from dl- $\alpha$ -tocopherol, dibutylhydroxytoluene, butylhydroxyanisole, and propyl gallate, particularly preferably, dl- $\alpha$ -tocopherol.

**Please replace paragraph [0026] with the following amended paragraph:**

"Fat and oil" used in the present invention include medium-chain ~~triglyceride~~triglycerides (hereinafter, also referred to as "MCT"), tricaprilin, caproic acid, caprylic acid, capric acid, oleic acid, linoleic acid, linolenic acid, and plant oil. In this context, the plant oil includes coconut oil, olive oil, rapeseed oil, peanut oil, corn oil, soybean oil, cottonseed oil, grape oil, and safflower oil. The fat and oil are preferably MCT, tricaprilin, caproic acid,

caprylic acid, or capric acid free of unsaturated fatty acid, particularly preferably MCT.

**Please replace paragraph [0056] with the following amended paragraph:**

HPLC analysis conditions

Column: YMC-Pack ODS AM-303 (250 × 4.6 mm, 5 μm),  
manufactured by YMC Co., Ltd.

Mobile phase: acetonitrile/water =1:1

Flow rate: 1.2 mL/min

Peak detection: UV 265 nm, RI

Column temperature: 30°C

(Results)

The chromatograms obtained by HPLC measurement of the drug solution that ~~has been~~was left for 33 days under the conditions of 40°C/75% RH are shown in Figures 1 and 2. In the RI-chromatogram, minor peaks were detected at around both 16 minutes and 24 minutes, in addition to a main peak corresponding to ED-71 and a minor peak corresponding to the pre form of ED-71 at around 17 minutes. These two peaks ~~are~~were not detected in a sample before storage under 40°C/75% RH, and the peaks detected in RI-HPLC are derived from <sup>3</sup>H-ED-71. Therefore, it was suggested that these two components are main degradation products of ED-71. The peak eluted at around 16

minutes was almost identical to the position of the main eluted peak detected in the analysis of a standard solution of the tachysterol form under the same HPLC conditions, and is therefore considered to be derived from the tachysterol form. The peak eluted at around 24 minutes was almost identical to the position of the main eluted peak detected in the analysis of a standard solution of the trans form under the same HPLC conditions, and is therefore considered to be derived from the trans form.